

2517-96

11/17/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

NOV 17 2008

Susan Craft  
Regulatory Specialist  
Sergeant's Pet Care Products, Inc.  
26615 S. 158<sup>th</sup> Plaza  
Omaha, NE 68130-1770

Subject: Label Notification(s) for Pesticide Registration Notices 2007-4 and 98-10  
Updated Warranty and Disclaimer Statements

Alternate Brand Name:

1. Sergeant's Vetscription Miteaway Ear Mite and Tick Treatment for Dogs
2. Sergeant's Vetscription Miteaway Ear Mite and Tick Treatment for Cats
3. Sergeant's Vetscription Miteaway Ear Mite and Tick Treatment for Dogs and Cats
4. Sentry HC Earmitfree Ear Miticide for Dogs
5. Sentry HC Earmitfree Ear Miticide for Cats
6. Sentry HC Earmitfree Ear Miticide for Dogs and Cats

Dear Ms. Craft:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 and 98-10 dated October 28, 2008 for:

**EPA Registration 2517-96**

**Sergeant's Ear Mite & Tick Control for Dogs & Cats**

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10 and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Nicole Williams of my staff at 703-308-8893.

Sincerely,



Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs



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United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2517-96	2. EPA Product Manager Richard J. Gebken	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Ear Mite & Tick control for [Dogs] [&] [Cats]	PM# 10	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 2625 S. 158th Plaza, Omaha, NE 68130-1770 <input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
NOTIFICATION OF ALTERNATE BRAND NAMES PER PR NOTICE 98-10: SEE ATTACHED LETTER AND MASTER LABEL DATED OCTOBER 28, 2008.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 3 fl. oz.	No. per container 1	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 3 fl oz		5. Location of Label Directions <input type="checkbox"/> FRONT Label <input checked="" type="checkbox"/> BACK Label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper, glued Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Susan Craft	Title Regulatory Specialist	Telephone No. (Include Area Code) 402-938-7021
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Specialist	
4. Typed Name Susan Craft	5. Date 28 October 2008	

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SCraft@SERGEANTS.com

11/14/2008 12:04 PM

To Nicole Williams/DC/USEPA/US@EPA

cc

bcc

Subject Re: Your EPA Notification

Per your request:

Notification of Alternate Brand Names (highlighted on revised Master Label) per PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.

Notification of label changes relative to PR Notice 2007-4.

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Susan Craft  
Sergeant's Pet Care Products, Inc.  
2625 S. 158th Plz.  
Omaha, NE 68130  
(402) 938-7021  
(402) 938-7121 (fax)

Williams.Nicole@epamail.epa.gov

To



Sergeant's Pet Care Products, Inc.

2625 South 158th Plaza • Omaha, NE 68130-1770 • Telephone 402.938.7000 • Fax 402.938.7099 • www.sergeants.com

October 28, 2008

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460-0001

SUBJECT: EPA Letter dated October 21, 2008  
Sergeant's Ear Mite & Tick Control for Dogs & Cats, EPA Reg. No. 2517-96

Dear Mr. Gebken:

In reference to your letter dated October 21, 2008 regarding label revisions for Sergeant's Ear Mite & Tick Control for Dogs and Cats (EPA Reg. No. 2517-96), please find the following:

1. Language has been replaced according to PR Notice 2007-4, in the first part of the "Disposal:" subsection with: **"Pesticide Disposal: If empty: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available."**
2. "Warranty & Disclaimer" section is in accordance with the guidance documents entitled "Guidance on Warranty Statements" dated October 17, 2006. Enclosed is application and approval for amendment to "Warranty & Disclaimer " section for EPA. No. 2517-95 dated August 18, 2008. This "Warranty & Disclaimer" section has been previously reviewed and adjusted twice by your office.
3. Notification application for the highlighted ABNs.

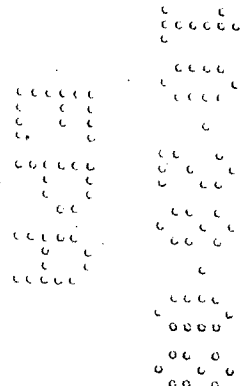
Enclosed are the following documents in support of the above changes.

- a. 2 copies of revised master label, one with highlighted changes.
- b. 1 copy of EPA letter dated October 21, 2008
- c. 1 copy of EPA SAL dated August 18, 2008 for EPA Reg. No. 2517-95 in support of the "Warranty & Disclaimer" requested language change.
- d. Notification application for additional ABNs

If you have any questions, please contact me by phone at 402-938-7021 or by email at [scraft@sergeants.com](mailto:scraft@sergeants.com). A stamped, self-addressed envelope is enclosed for your convenience in returning a copy of the approved notification.

Sincerely,

Susan Craft  
Regulatory Affairs Specialist  
Sergeant's Pet Care Products, Inc.



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# Sergeant's Master Label

28 October 2008 2<sup>nd</sup> Notification  
Information in [ ] is optional.

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EPA Reg. No. 2517-96  
EPA SAL 21 October 2008

## FRONT PANEL

## EAR MITE & TICK CONTROL

**Pyrethrins & Piperonyl butoxide, technical**

[Optional text appears in brackets – the final label may include some or all of the optional text on front, back or side label panels]

### {Brand Name} Ear Mite & Tick Control For [Dogs] [&] [Cats]

- {ABN: Sergeant's® Vetscription Miteaway Ear Mite and Tick Treatment for Dogs}
- {ABN: Sergeant's® Vetscription Miteaway Ear Mite and Tick Treatment for Cats}
- {ABN: Sergeant's® Vetscription Miteaway Ear Mite and Tick Treatment for Dogs and Cats}
- {ABN: Sergeant's® Vetscription Ear Mite for Dogs}
- {ABN: Sergeant's® Vetscription Ear Mite for Cats}
- {ABN: Sergeant's® Vetscription Ear Mite for Dogs and Cats}
- {ABN: Sentry HC Earmitefree Ear Miticide for Dogs}
- {ABN: Sentry HC Earmitefree Ear Miticide for Cats}
- {ABN: Sentry HC Earmitefree Ear Miticide for Dogs and Cats}
- {ABN: Sentry HC Mite X for Dogs}
- {ABN: Sentry HC Mite X for Cats}
- {ABN: Sentry HC Mite X for Dogs and Cats}

## NOTIFICATION

NOV 17 2008

- [Contains Aloe]
- [For use on [Dogs] [&] [Cats]]
- [To] [Kills Ticks and Ear Mites]

{Ingredient Statement may be on front or back label}

### ACTIVE INGREDIENTS:

Pyrethrins .....	0.06%
Piperonyl Butoxide Technical * .....	0.60%

<b>OTHER INGREDIENTS**:</b> .....	<b>99.34%</b>
<b>[TOTAL]</b>	<b>100.00%</b>

\* Equivalent to 0.480% of (butylcarbityl) (6-propylpiperonyl) ether and up to 0.12% related compounds.

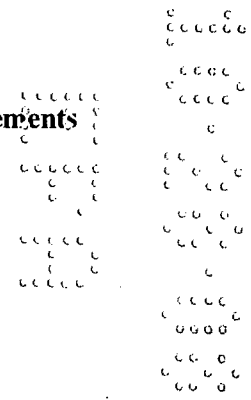
\*\*Contains petroleum distillates.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See [Back][or][Side] Panel[s] for Additional Precautionary Statements

NET [WEIGHT] [CONTENTS]      XXX oz (XXX mL)



# Sergeant's Master Label

28 October 2008 2<sup>nd</sup> Notification  
Information in [ ] is optional.

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EPA Reg. No. 2517-96  
EPA SAL 21 October 2008

**BACK PANEL**

**EAR MITE & TICK CONTROL**  
**Pyrethrins & Piperonyl butoxide, technical**

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**READ ENTIRE LABEL BEFORE EACH USE. SHAKE WELL BEFORE USE.**  
**USE ONLY ON [DOGS] [CATS] or [DOGS OR CATS]**

To be used as an aid in eliminating mites and ticks in the ears of [dogs] [cats] or [dogs or cats] and for relief from itching caused by such conditions. Apply 5 drops into ears twice daily until ticks and mites are eliminated. Do not allow children to apply this product. Use other EPA approved products for treatment of mites and ticks outside the ear.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

**HUMANS:** Contains Petroleum Distillates. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing vapor or spray mist. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

**ANIMALS:** Do not use on animals under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing or medicated animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

### FIRST AID

<b>IF SWALLOWED</b>	<ul style="list-style-type: none"><li>• Immediately call a poison control center or doctor.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Have a person sip a glass of water if able to swallow.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>

**NOTE TO PHYSICIAN:** Contains petroleum distillates. Vomiting may cause aspiration pneumonia.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.

# Sergeant's Master Label

28 October 2008 2<sup>nd</sup> Notification  
Information in [ ] is optional.

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EPA Reg. No. 2517-96  
EPA SAL 21 October 2008

**BACK PANEL**

**EAR MITE & TICK CONTROL**  
**Pyrethrins & Piperonyl butoxide, technical**

## STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Keep this product in original container in an area inaccessible to children and pets and away from heat and sunlight

**PESTICIDE DISPOSAL: If empty:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

**If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

## [WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. [[The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Unintended consequences may result because of such factors as weather conditions, presence or absence of other materials, or the manner of application, all of which are beyond the control of Sergeant's.] ] Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller disclaims any liability whatsoever for special, incidental, or consequential damages resulting from the use of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: Sergeant's Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738  
Non-Emergency call 1-800-224-PETS (7387) [Made in USA]

Distributed by:  
Sergeant's Pet Care Products, Inc.  
Omaha, NE 68130

EPA Reg. No. 2517-96  
EPA Est. No. XXXXX-XX-XX  
[lot, date & label code] [UPC CODE]

{END - BACK / SIDE PANEL}